IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. 1:23-00152-CFC
VANDA PHARMACEUTICALS INC., Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	C.A. No. 1:23-00153-CFC

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR JUDGMENT ON THE PLEADINGS

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I. INTRODUCTION

Defendants Apotex Inc. and Apotex Corp. ("Apotex") and Teva Pharmaceuticals USA, Inc. ("Teva") move for judgment on the pleadings that claims 1-3 of U.S. Patent No. 11,285,129 ("the '129 patent") are invalid as obvious as a matter of law based on collateral estoppel or, in the alternative, that claims 1-3 are not infringed.

II. NATURE AND STAGE OF THE PROCEEDINGS

A. The Pending Actions

Vanda filed these consolidated actions against Apotex and Teva in the District of New Jersey on December 27, 2022. *See* D.I. 1. Two days after filing its Complaint, Vanda moved for a temporary restraining order ("TRO") seeking to enjoin Defendants from launching their generic tasimelteon products. C.A. No. 23-153, D.I. 5; C.A. No. 23-152, D.I. 7. In opposing Vanda's motion, Defendants filed a cross-motion to transfer the case to this Court (C.A. No. 23-153, D.I. 18; C.A. No. 23-152, D.I. 23), which the New Jersey court granted (C.A. No. 23-153, D.I. 47; C.A. No. 23-152, D.I. 53). In doing so, the New Jersey court relied on the fact that this Court "ha[d already] overseen comprehensive litigation relating to tasimelteon and the applicable family of patents for over four years." C.A. No. 23-153, D.I. 47; C.A. No. 23-152, D.I. 53 at 14. Given this Court's experience and familiarity with the factual and legal issues, the New Jersey court also opted to

allow this Court to decide Vanda's motion for a TRO. *See id.* at 4, n.3. But five days after the transfer, Vanda withdrew its motion for a TRO. C.A. No. 23-153, D.I. 52; C.A. No. 23-152, D.I. 58.

Defendants filed their Answers, Affirmative Defenses, and Counterclaims on February 27, 2023. C.A. No. 23-153, D.I. 56; C.A. No. 23-152, D.I. 63. On March 13, 2023, Vanda filed a Motion to Strike Affirmative Defenses And To Dismiss Counterclaims Premised on the January 2021 Scheduling Conference (C.A. No. 23-153, D.I. 67-69; C.A. No. 23-152, D.I. 74-76), to which Defendants responded on April 10, 2023 (C.A. No. 23-153, D.I. 74; C.A. No. 23-152, D.I. 82).

B. The Prior Litigation Involving Related Patents

Before asserting the '129 patent here, Vanda previously sued Apotex and Teva in this Court alleging infringement of fourteen other Orange Book-listed patents for Vanda's Hetlioz® product. *See* Case No. 18-651 (CFC) (consolidated) (the "Prior Litigation"). Among the patents asserted by Vanda were U.S. Patent Nos. RE46,604 ("the RE604 patent") and 10,149,829 ("the '829 patent"), both of which are related to the '129 patent and share a common specification. Following a four-day bench trial, this Court found claim 3 of the RE604 patent and claim 14 of the '829 patent invalid as obvious. *See Vanda Pharm., Inc. v. Teva Pharm. USA, Inc.*, Case No. 18-651-CFC, 2022 WL 17593282 (D. Del. Dec. 13, 2022). Final judgment was entered on December 14, 2022. *See Vanda Pharm., Inc. v. Teva*

Pharm. USA, Inc., C.A. No. 18-651-CFC, D.I. 338 (D. Del. Dec. 14, 2022).

Important here, this Court previously found that methods of treating Non-24 (i.e., Non-24-Hour Sleep-Wake Disorder) by administering 20 mg of tasimelteon once daily about one-half hour to about one-and-one-half hours before a target bedtime are obvious over the prior art. *See* 2022 WL 17593282, *9-*10, *15-*17.

III. SUMMARY OF THE ARGUMENT

The ’129 patent’s claimed methods of administering tasimelteon are invalid over the same prior art and for the same reasons that this Court previously found the asserted claims of the related RE604 and ’829 patent invalid in the Prior Litigation. The only difference between the claims of the ’129 patent and those of the RE604 and ’829 patents is a requirement to determine “whether a patient is being treated with a [beta-blocker],” which adds no patentable distinction to the claims at issue.

In the alternative, to the extent Vanda argues and the Court agrees that the asserted claims are not invalid under collateral-estoppel principles because they require discontinuing a beta-blocker and then administering tasimelteon, Defendants do not induce infringement of the ’129 patent as a matter of law. Defendants’ FDA-approved labels do not instruct physicians to discontinue treatment with a beta-blocker and then administer tasimelteon.

IV. THE ASSERTED '129 PATENT

The '129 patent is titled "Treatment of Circadian Rhythm Disorders" and is directed to a purportedly improved "method of administering tasimelteon to a patient" in which a physician first determines "whether the patient is being treated with a beta-adrenergic receptor antagonist" (i.e., a beta-blocker).

The three issued claims of the '129 recite the following:

> 1. In a method of administering tasimelteon to a patient, the improvement comprising:
>
> determining whether the patient is being treated with a beta-adrenergic receptor antagonist; and
>
> in the case that it is determined that the patient is not being treated with a beta-adrenergic receptor antagonist, administering to the patient 20 mg of tasimelteon once daily about one-half hour to about one-and-one-half hours before the target bedtime; or
>
> in the case that it is determined that the patient is being treated with a beta-adrenergic receptor antagonist;
>
> instructing the patient to cease treatment with the beta-adrenergic receptor antagonist; and then
>
> administering to the patient 20 mg of tasimelteon once daily about one-half hour to about one-and-one-half hours before the target bedtime.
>
> 2. The improvement of claim 1, wherein the beta-adrenergic receptor antagonist is selected from a group consisting of: alprenolol, altenolol, carvedilol, metoprolol, and propranolol.
>
> 3. The improvement of claim 2, wherein the patient is suffering from Non-24-Hour Sleep-Wake Disorder.

D.I. 1, Exh. A at 36 (emphasis added).

Claim 1 of the '129 patent is very similar to claim 14 of the '829 patent that was at issue in the Prior Litigation, with one important distinction: while claim 14 of the '829 patent requires "discontinuing treatment with the strong CYP1A2 inhibitor" (2022 WL 17593282, *8), claim 1 of the '129 patent recites "instructing the patient to cease treatment with the [beta-blocker]" as only one of two possible options in practicing the claimed method. Thus, claim 1 of the '129 patent is directed to a "conditional" method whereby a physician can take either of two courses of action:

> 1. If, on the one hand, the patient is not taking a beta-blocker, then tasimelteon is administered according to the prior-art method in which 20 mg of tasimelteon is administered once daily about one-half hour to about one-and-one-half hours before a target bedtime;

or,

> 2. If, on the other hand, it is determined that the patient is taking a beta-blocker, then the physician must instruct the patient to "cease treatment" with the beta-blocker, and then administer tasimelteon by the same prior art method in which 20 mg of tasimelteon is administered once daily about one-half hour to about one-and-one-half hours before a target bedtime.

Importantly, these two "conditional" steps of the claimed method are joined by "or," which means that, if the first step is practiced, then the method ends and the second step is not reached. To show invalidity of this type of claim, it is necessary only to provide evidence that one of the optional limitations is found in the prior art. *See, e.g., Brown v. 3M*, 265 F.3d 1349, 1352-53 (Fed. Cir. 2001) (a claim written in the alternative is anticipated if any of the optional limitations is in

the prior art); *Ex Parte Schulhauser*, No. 2013-007847, 2016 WL 6277792, *9 (P.T.A.B. Apr. 28, 2016).

Further, no claim construction is required to reach the conclusion that "or," as that term is used in claim 1 of the '129 patent, does not mean "and," as such a term needs no construction when its "plain and ordinary meaning . . . is clear." *See, e.g.*, *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015). However, should Vanda contend that claim construction is necessary, the court must either accept Vanda's proposed constructions or resolve any claim construction dispute before ruling on this Rule 12(c) motion. *See MyMail, Ltd. v. ooVoo, LLC*, 934 F.3d 1373, 1379 (Fed. Cir. 2019).

V. RELEVANT LEGAL STANDARDS

A. Judgment on the Pleadings

Under Rule 12(c), a party may move for judgment "[a]fter pleadings are closed but within such time as not to delay trial." Judgment on the pleadings will be granted "if it is clearly established that no material issue of fact remains to be resolved and that the movant is entitled to judgment as a matter of law." *Rodriguez v. Stevenson*, 243 F. Supp. 2d 58, 62 (D. Del. 2002). A Rule 12(c) motion is especially useful where, as here, "only questions of law remain to be decided by the district court." 5C Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure(s)* 1367 (2004) (citations omitted).

In evaluating a motion for judgment on the pleadings, a court may consider the pleadings, exhibits attached to the pleadings, matters of public record, and any documents "integral to or explicitly relied upon" in the pleadings. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). The Court may also take judicial notice of the factual record of the Prior Litigation. *See Oneida Motor Freight, Inc. v. United Jersey Bank*, 848 F.2d 414, 416 n.3 (3d Cir. 1988).

B. Invalidity Based on Collateral Estoppel

"[W]here a patent has been declared invalid in a proceeding in which the 'patentee has had a full and fair chance to litigate the validity of his patent,' . . . the patentee is collaterally estopped from relitigating the validity of the patent." *Miss. Chem. Corp. v. Swift Agric. Chems. Corp.*, 717 F.2d 1374, 1376 (Fed. Cir. 1983) (quoting *Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 333 (1971)). Collateral estoppel is not limited "to patent claims that are identical. Rather, it is the identity of the issues that were litigated that determines whether collateral estoppel should apply." *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013).

Collateral estoppel may also operate to bar re-litigation of common issues in actions involving different, but related, patents. *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 1310 (Fed. Cir. 2001). Whether the difference between the patent claims materially alters the question of patentability is a legal

conclusion based on underlying facts. *Google LLC v. Hammond Dev. Int'l, Inc*., 54 F.4th 1377, 1381 (Fed. Cir. 2022).

The Supreme Court has endorsed Rule 12(c) motions for disposing patent cases through collateral estoppel. *Blonder-Tongue*, 402 U.S. at 348 ("[T]he accused infringer should have available as an estoppel defense that can be pleaded affirmatively and determined on a pretrial motion for judgment on the pleadings or summary judgment.").

The Third Circuit has identified "four standard requirements for the application of collateral estoppel." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d. Cir. 2006).[1] These are: (1) the identical issue was previously litigated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from re-litigating the issue was fully represented in the previous action. *Id*. (citations, quotations omitted). Once the four criteria are met, a court has no discretion to not apply collateral estoppel on equitable "considerations of justice and equity." *Biogen Int'l GMBH v. Amneal Pharm. LLC*, Case No. 17-823 (MN), 2020 WL 5549084, *8 (D. Del. Sept. 16, 2020).

[1] The Federal Circuit applies the law of the regional circuit to issue-preclusion determinations. *Intellectual Ventures I LLC v. Capital One Fin. Corp*., 850 F.3d 1322, 1137 (Fed. Cir. 2017).

VI. ARGUMENT

A. Vanda is Collaterally Estopped from Asserting The '129 Patent Against Defendants

Vanda is barred by the collateral estoppel effect of this Court's obviousness findings in the Prior Litigation from asserting the '129 patent against Defendants because "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander*, 458 F.3d at 249 (citations, quotations omitted).

In the Prior Litigation, this Court held claim 3 of the RE604 patent and claim 14 of the '829 patent invalid as obvious. 2022 WL 17593282, *9-*10, *15-*17. The '129 patent at issue here is a continuation application of the RE604 and '829 patents, which share a common specification with the '129 patent. *See* D.I. 1, Exh. A at 1.[2] In finding the claims of the RE604 and '129 patents invalid as obvious, this Court made factual findings that methods of treating Non-24 (i.e., Non-24-Hour Sleep-Wake Disorder) by administering 20 mg of tasimelteon once daily about one-half hour to about one-and-one-half hours before a target bedtime were obvious in light of the prior art. *See* 2022 WL 17593282, *9-*10, *15-*17.

There can be no dispute that the obviousness of the related RE604 and '829

[2] The RE604 patent is a Reissue of U.S. Patent No. 8,785,492, which is referenced on the face of the '129 patent.

patents was actually litigated in the Prior Litigation, or that the validity of the RE604 and '829 patents was necessary to this Court's opinion and entry of final judgment. Nor can Vanda credibly dispute that it was fully represented as a party in that proceeding. Thus, the sole issue as to whether collateral estoppel applies to preclude Vanda's claims in this action is whether the issue of invalidity of the claims of the '129 patent is "substantially identical" to that decided with respect to the RE604 and '829 patents in the Prior Litigation.

1. This Court Has Already Found the Operative Method Steps Claimed in the '129 Patent Obvious in Light of the Prior Art

Claim 1 of the '129 patent purports to be an "improvement" over prior-art methods of "administering tasimelteon to a patient." However, this Court found that the dose of tasimelteon (20 mg), the patient population (Non-24 patients, as recited in claim 3), and the timing of administration (once daily about 30 to about 90 minutes before a target bedtime) required by the claims of the '129 patent were all disclosed in the prior art. *Vanda*, 2022 WL 17593282, *9-*10, *15-*17. Thus, the only element of claim 1 of the '129 patent that distinguishes it from the claims of the RE604 and '829 patents that were found obvious is "determining whether the patient is being treated with [a beta-blocker]."

Importantly, because claim 1 of the '129 patent (and claims 2-3 that depend therefrom) uses the conditional transition phrase "or," that claim is invalid if either

of the two optional methods is taught or suggested by the prior art. *Brown*, 265 F.3d at 1352-53 (a claim written in the alternative is invalid if any of the optional limitations is in the prior art); *Ex Parte Schulhauser*, 2016 WL 6277792 at *9 (finding invalid as obvious a conditional method claim that presented two optional steps where evidence of one of the claimed options was found in the prior art). And one of the two options here—administering 20 mg tasimelteon once daily about one-half hour to about one-and-one-half hours before bedtime—is precisely the method this Court already found obvious. Specifically, while the wording of the claims of the ’129 patent is not identical to those claims of the RE604 and ’829 patents that were held invalid as obvious in the Prior Litigation, the issues are the same—specifically, whether administering 20 mg of tasimelteon to a Non-24 patient once daily 0.5 to 1.5 hours before a target bedtime was obvious. *See, e.g.*, *Ohio Willow Wood*, 735 F.3d at 1342 (“Our precedent does not limit collateral estoppel to patent claims that are identical. Rather, it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply.”)

Here, collateral estoppel applies because the only new element required by claims 1-3 of the ’129 patent (i.e., the “determining” step) adds no patentable weight to an otherwise invalid method, and in any event is indisputably disclosed in the prior art.

a. The "determining" step should receive no patentable weight because it does not modify the claimed method of administering tasimelteon, which this Court found obvious over the prior art

Claims 1-3 of the '129 patent are invalid based on principles of collateral estoppel because the "determining" step does nothing to modify the prior art method of administering tasimelteon recited by the first conditional step of claim 1. Where a claim element does not modify the manner in which a prior-art method of administering a drug is practiced, that element does not render the claim patentable. *See King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1278-79 (Fed. Cir. 2010).

In *King*, claims directed to methods of administering a drug (metaxalone) with food in order to increase bioavailability were found invalid on summary judgment because some of the claims merely required "informing" the patient of the increased bioavailability. *See id*. There, the relevant question was "whether the additional instructional limitation . . . has a 'new and unobvious functional relationship' with the known method of administering metaxalone with food." *In re Kao*, 639 F.3d 1057, 1072 (Fed. Cir. 2011) (discussing *King*, quoting *In re Ngai*, 367 F.3d 1336, 1338 (Fed. Cir. 2004)). Further, in *King*, the accused patent infringer was not required to introduce evidence that the "informing" limitation was disclosed in the prior art because an otherwise invalid method does not become patentable by including such a "nonpatentable" limitation. *Id*. at 1278.

King also analogized the "nonpatentable" method of "informing" to "printed matter" that does not functionally relate to the practice of a method that was otherwise disclosed in the prior art. *See id*. at 1278-79.

Similarly, in *Praxair Distr., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, claims that required "determining that a neonatal patient has [a] preexisting" condition, and then "evaluating the potential benefit" of treatment with the claimed drug (inhaled nitric oxide) were found to lack patentable weight. 890 F.3d 1024, 1033 (Fed. Cir. 2018). These steps, the court held, were "no more than a 'think about it' step." *Id.*

Here, claim 1 of the '129 patent merely requires that a physician determine whether a patient is taking a beta-blocker and then administer tasimelteon by a method that was found invalid in the Prior Litigation. As in *King*, the determining step, as applied to the first conditional method of claim 1, adds no new and non-obvious element to the recited method because it does not in any way change the prior-art method of administering tasimelteon.[3] And, as in *Praxair*, the determining step can be viewed as no more than a requirement for a doctor to obtain information, "think about it," and then administer tasimelteon by a method that has

[3] Defendants do not concede that the second "conditional" step recited by claim 1 (i.e., discontinuing treatment with a beta-blocker and then administering tasimelteon) adds any patentable subject matter. But that question is not relevant here; because Vanda chose to draft claim 1 using conditional language, all that is required is that one of the conditional methods is found in the prior art.

already been found invalid.

Claim 2 is similarly invalid because, as applied to the first conditional step of claim 1, it merely recites a list of known beta-blockers that a patient is not taking. Claim 2 likewise should receive no patentable weight because the limitations have no actual effect on the method of administering recited in the first conditional step of claim 1. Finally, claim 3 recites that the patient has Non-24, which this Court found was explicitly disclosed in the prior art. *See* 2022 WL 17593282, *9-*10, *15-*17.

For these reasons, claims 1-3 should be found invalid based on collateral estoppel because the "determining" step required by claim 1 does not render patentable an otherwise invalid method of administering tasimelteon.

b. The "determining" step is indisputably not new

Even if the "determining" step has patentable weight, that does not affect the obviousness analysis because there can be no genuine dispute that this step is not new. The "determining" step of claim 1 of the '129 patent merely requires a doctor to find out if a patient is taking a beta-blocker. As anyone who has been to a doctor's office knows, every patient questionnaire asks what medications a patient is currently taking.[4] Indeed, the '129 patent itself admits that beta-blockers "are known to reduce endogenous levels of melatonin." D.I. 1, Exh. A at 8:65 – 9:6.

[4] *See, e.g.*, http://www.charlydmiller.com/COMM/medquestions.html

Given that this knowledge was admittedly in the prior art, there should be no dispute that it would be obvious to at least "determine" whether a patient to whom one intends to administer a melatonin agonist is currently taking a beta-blocker.

Further, in finding the asserted claims of the RE604 and '829 patents obvious, this Court relied on prior art that disclosed the use of tasimelteon in clinical trials to evaluate its use in a wide range of conditions, including the treatment of Non-24, insomnia, and the ability to phase-shift. *See* 2022 WL 17593282, *9-*10, *15-*17 (citing Lankford, Hardeland, the '244 publication, and Vanda's prior-art clinical trial protocol). Both Lankford and Vanda's prior art clinical study disclose the administration of tasimelteon to at least some patients who were not taking a beta-blocker. *See id.*, *10, *12-*13.

As discussed above, claim 2 merely recites a list of beta-blockers that were known in the prior art, and claim 3 requires that the patient has Non-24. There is simply nothing new in these claims that makes them patentable over the claims of the RE604 and '829 patents that this Court previously found invalid.

For these reasons, claims 1-3 should be found invalid based on collateral estoppel because the "determining" step—even if it is a limitation of claim 1—adds nothing that makes these claims patentable over the prior art of record in the Prior Litigation.

2. Vanda's Pending Appeal Does Not Provide a Basis to Deny This Motion

The fact that Vanda has appealed this Court's final judgment is no basis to deny this motion. In *Galderma Labs. Inc. v. Amneal Pharm., LLC*, this Court granted a motion for judgment on the pleadings based on the collateral estoppel effect of its noninfringement order in another case filed by the same plaintiff. 921 F. Supp. 2d 278, 281-82 (D. Del.). In so doing, the Court found the pendency of an appeal of its prior order had no bearing on it collateral estoppel effect. *Id*. at 281; *see also Pharmacia & Upjohn Co. v. Mylan Pharm. Inc*., 170 F.3d 1373, 1381 (Fed. Cir. 1999) (well-established law that the pendency of any appeal has no bearing on the binding effect of a trial court's decision). Therefore, any uncertainty about the outcome of Vanda's appeal of this Court's entry of final judgment in the Prior Litigation should not be cause to deny Defendants' motion. *Galderma*, 921 F. Supp. 2d at 282.

B. In The Alternative, Defendants Are Entitled to Judgment on the Pleadings of Non-Infringement

To the extent Vanda argues that Defendants must show that both of the options recited in claim 1 must be found in the prior art to prove invalidity, Defendants believe that is an erroneous reading of the claim for the reasons explained above. Were the Court to agree with such a reading, however, that would render it impossible for Vanda to prove infringement. Specifically, Defendants'

labels do not instruct patients to cease treatment with a beta-blocker and then take tasimelteon, as required by the second conditional method step of claim 1 of the '129 patent.

Defendants do not and will not directly infringe the '129 patent because, as pharmaceutical companies, they do not administer tasimelteon to patients. Vanda must therefore rely on a theory of induced infringement. To show inducement, Vanda must show that Teva and Apotex "possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc). "The question is not . . . whether a user following the instructions may end up using the device in an infringing way. Rather, it is whether [the] instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009).

To meet this intent requirement, Vanda asserts that physicians reading the FDA-approved label for tasimelteon "would understand [it] to instruct the reader to avoid the use of beta-blockers." *E.g.*, D.I. 1, ¶ 36. A closer look at the language in the label that Vanda points to proves otherwise. Apotex's and Teva's labels for their tasimelteon products only state that "[b]eta-adrenergic receptor antagonists have been shown to reduce the production of melatonin via specific inhibition of beta-1 adrenergic receptors. Nighttime administration of beta-adrenergic receptor

antagonists may reduce the efficacy of tasimelteon." C.A. No. 23-153, D.I. 5-9 at 5[5]. This, of course, does not direct anyone to stop using beta-blockers. Rather, the language in Apotex's and Teva's labels concerns the time at which a beta-blocker may be administered, and that "[n]ighttime administration of [beta-blockers] may reduce the efficacy of tasimelteon." *Id*.

In the Prior Litigation, the same Section 7 of Defendants' labels were at issue concerning whether Defendants induced infringement of the '829 patent by instructing physicians to discontinue administering a CYP1A2 inhibitor prior to administering tasimelteon. *See* Trial Tr. (3/29/2022) 516:1 – 518:14 (Winkelman), Ex. A. There, this Court heard testimony that instructions in Defendants' labels to "avoid" co-administration of tasimelteon with a CYP1A2 inhibitor would not result in patients discontinuing treatment with a CYP1A2 inhibitor prior to administering tasimelteon. Here, the language in Defendants' labels permits a physician to avoid a drug-drug interaction between a beta-blocker and tasimelteon by simply instructing that a beta-blocker be given during the daytime rather than at nighttime. A physician confronted with a patient taking a beta-blocker could also increase the dose of tasimelteon to counteract any reduced efficacy. Thus, Defendants' labels permit "substantial non-infringing uses," which supports a finding of non-infringement as a matter of law. *See HZNP Meds. LLC v. Actavis*

[5] This cite is to Apotex's label. The wording in Teva's label is identical.

Lab'ys UT, Inc., 940 F.3d 680, 702 (Fed. Cir. 2019) (affirming summary judgment of no inducement).

Vanda's complaint alleges that "at least some doctors would counsel some patients taking certain beta-blockers to cease their use of those beta-blockers when taking" Defendants' generic tasimelteon products. D.I. 1 at ¶ 37. However, even if this assertion is true, it is black-letter law that "[t]he mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient." *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). And "vague label language cannot be combined with speculation about how physicians may act to find inducement." *Id.* at 632; *HZNP*, 940 F.3d at 702 (evidence that "some users might infringe" is insufficient to show inducement; patentee must "establish that 'the proposed label instructs users to perform the patented method'") (quoting *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010)).

Moreover, Vanda's own expert has already conceded in this case that beta-blockers are used for very serious conditions (including heart failure, anxiety, tremors, and heart attack). C.A. No. 23-153, D.I. 5-2; C.A. No. 23-152, D.I. 7-2 (Combs Dec.) ¶ 55. There are thus very legitimate reasons why a physician would not want to discontinue their use—a fact Vanda's infringement theory ignores.[6]

[6] Vanda's expert suggests (at ¶ 57) that a physician could prescribe verapamil in

Simply put, prescribing physicians could faithfully follow the instructions on Defendants' label without discontinuing beta-blocker use. For that reason, Vanda cannot establish the specific intent required for actively inducing infringement. *See, e.g.*, *Takeda*, 785 F.3d at 632-33 (finding no induced infringement where it was undisputed that the label's language allowed for "a host of [non-infringing] alternatives" and the plaintiff could not show "that physicians would forego these alternatives" and choose the infringing course of action); *HZNP*, 940 F.3d at 702 (finding no induced infringement where the label's instructions "d[id] not require" practicing the claimed method, which "reflect[ed] that the product ha[d] substantial noninfringing uses," precluding a finding of specific intent to induce infringement).

VII. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion for judgment on the pleadings.

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place of a beta-blocker—implying that verapamil would be co-administered with tasimelteon. That directly contradicts his sworn testimony to this Court. At trial in the Prior Litigation, Dr. Combs testified that Defendants' labels taught that a physician should avoid co-administering tasimelteon with a strong CYP1A2 inhibitor, including verapamil. *See* Trial Tr. (3/28/2022) 233:3–234:11 (Combs), Ex. B (testifying that Teva's and Apotex's labels instruct to discontinue use of strong CYP1A2 inhibitors before beginning tasimelteon); *id.* 248:25–249:2 (testifying that verapamil is a strong CYP1A2 inhibitor covered the claim). Here—when Vanda needs a different opinion about whether a doctor would co-administer verapamil and tasimelteon—Dr. Combs takes the exact opposite position.

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CERTIFICATE OF COMPLIANCE

In compliance with this Court's November 22, 2022 Standing Order Regarding Briefing in All Cases, Defendants certify that the foregoing Opening Brief In Support Of Their Motion For Judgment On The Pleadings is in Times New Roman 14-point font and includes a total 4,821 words excluding the cover page, Table of Contents, and Table of Authorities as determined using the word-count function in MSWord, and therefore complies with this Court's type, font, and word limitations.

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